UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

B.F. a minor, BETH FORBES, individually and as next friend of B.F. and THOMAS FORBES, individually and as next friend of B.F.,	)	
Plaintiffs	)	No. 4:12-CV-1760 CAS
vs.	)	JURY TRIAL DEMANDED
ABBOTT LABORATORIES, INC., et al	)	
Defendants	)	

PLAINTIFFS' TRIAL BRIEF REGARDING THE SCOPE OF DEFENDANT ABBOTT LABORATORIES, INC.'S DUTY TO WARN

Plaintiff B.F., a minor, Beth Forbes, individually and as next friend of B.F. and Thomas Forbes, individually and as next friend of B.F., respectfully submit this trial brief regarding the scope of Defendant Abbott Laboratories, Inc.'s ("Abbott's") duty to warn.

I. Summary

Plaintiffs file this brief to address issues relating to the proper interpretation of, and a potential inconsistency between, the Court's Memorandum and Orders denying Abbott's motions for summary judgment on Plaintiffs' failure to warn[1] and punitive damages[2] claims ("Summary Judgment Orders"), and the Court's Memorandum and Order granting, in part, Abbott's motion to exclude certain expert opinion testimony of Dr. Godfrey P. Oakley, Jr. ("Oakley Order").[3]

[1] March 31, 2016 Memorandum and Order, Dkt. No. 94.

[2] April 8, 2016 Memorandum and Order, Dkt. No. 102.

[3] May 6, 2016 Memorandum and Order, Dkt. No. 197.

Specifically, the Oakley Order appears to exclude Dr. Oakley's testimony that it was possible and reasonable for Abbott to have established a pregnancy registry dating back to the 1980s based on the notion that the relevant warning for Plaintiffs' claims is the 1 to 2 percent spina bifida warning in Abbott's Depakote label.[4] But, as the Court previously recognized in both Summary Judgment Orders—and in agreement with every other Court in prior Depakote cases addressing this issue—Plaintiffs have viable claims relating to the deficiencies in Abbott's warnings that are broader than just this spina bifida warning. As this Court previously noted in its Summary Judgment Orders, regardless of Abbott's spina bifida warning, under Missouri law "[t]here is a still a question of fact whether the warning was informationally deficient" based on the numerous other relevant, broader ways Plaintiffs allege Abbott's Depakote label was inadequate.[5]

Plaintiffs have proactively raised this clarification request because, notwithstanding the Court's recognition of Plaintiffs' broader claims in its Summary Judgment Orders, Plaintiffs anticipate Abbott will attempt to now use the Oakley Order as a basis for resuscitating its prior failed attempts to restrict Plaintiffs' failure to warn claims to just the spina bifida warning.[6]

II. Background and Clarification Request

In this case, Abbott has taken a narrow and inflexible interpretation of its duty to adequately warn or instruct under Missouri law. Plaintiffs acknowledge that when Dr. Raziya Mallya prescribed Depakote to Mrs. Forbes prior to Plaintiff B.F.'s conception, Abbott's

[4] *Id.* at 10-13.

[5] March 31, 2016 Memorandum and Order, Dkt. No. 94 at 6-9; April 8, 2016 Memorandum and Order, Dkt. No. 102 at 5-6.

[6] The import of this clarification is heightened because Plaintiffs anticipate Abbott will attempt to use the Oakley Order as an alleged basis to limit Plaintiffs' claims to just the spina bifida warning not only in this case, but in every future Depakote case involving a spina bifida injury. For example, within less than a week of receiving the Oakley Order, Abbott had already sent an e-mail to Judge Rosenstengel in the U.S. District Court for the Southern District of Illinois providing her with "notice" and a copy of the Oakley Order.

Depakote label identified a 1 to 2 percent chance of having a baby with spina bifida if taking Depakote, and further included certain general, class-wide statements regarding the teratogenicity of all anti-epileptic drugs, including Depakote. As this Court has already recognized, however, Plaintiffs have substantial evidence that Abbott's warning regarding Depakote use in pregnancy or by women of childbearing age was still deficient in several key respects. Plaintiffs' claims center on Abbott's failure to adequately warn prescribers about, among other deficiencies, the ***overall risk*** of birth defects associated with Depakote, the comparative ***overall risk*** of birth defects associated with Depakote compared with the other drugs used for the conditions Depakote was indicated, and "last line" treatment warnings Abbott should have provided based on Depakote's ***overall risk*** of birth defects and comparative teratogenicity.

Indeed, when a doctor prescribes a drug to a woman of childbearing age, she will consider the totality of the drug's danger to a fetus and all warnings that are relevant to the risk to a fetus. For this reason, as Plaintiffs have pointed out previously, drug companies have a duty to provide adequate warnings regarding the use of a drug by pregnant women or women of childbearing years, the potential dangers to a fetus, and indeed have obligations under federal regulations to do so.

This Court has already rejected Abbott's attempts to restrict Plaintiffs' claims to just "the spina bifida warning" in its Summary Judgment Orders. In its Order denying Abbott's motion for summary judgment on Plaintiffs' failure to warn claim, the Court stated:

> While Abbott is correct that Dr. Mallya testified that she knew of the risk of spina bifida, and advised Mrs. Forbes of the risk, this does not necessarily render the Depakote warning label adequate as a matter of law. There is a still a question of fact whether the warning was informationally deficient. In particular, it is questionable whether warning the patient of 1 to 2 percent chance of having a

> baby with spina bifida if taking Depakote fulfills Abbott's duty under Missouri law to properly warn the doctor of the dangers involved.[7]

In rejecting Abbott's confined approach to Plaintiffs' claims, the Court noted that Plaintiffs produced expert opinions to establish that, notwithstanding the spina bifida warning in the Depakote label, Abbott's label was inadequate for a **number of additional reasons** including, but not limited to: (i) Abbott's failure to include "a statement that Depakote should only be used as a 'last line' treatment (i.e., only if other treatment options have failed) in women of childbearing potential"; (ii) Abbott's failure "to provide current, complete and accurate information in the labeling and fail[ure] to correct obsolete data and information"; and (iii) Abbott's failure "to advise on the importance of contraceptive use."[8] Moreover, with respect to these inadequacies, the Court also noted Dr. Mallya's testimony that these additional warnings would have changed her approach to prescribing Depakote.[9]

This Court's Order denying Abbott's motion for summary judgment on Plaintiffs' claim for punitive damages similarly rejected Abbott's attempt to restrict the issues in this case to just spina bifida:

> Abbott argues that at the time Mrs. Forbes was prescribed Depakote, the label included a FDA-mandated black box warning regarding teratogenicity, and specifically warned of the risk of spina bifida, the very injury suffered by B.F. Because Abbott warned of the known risks and of the harm suffered by plaintiff, it argued that it cannot be found to have acted outrageously due to evil motive or reckless indifference to the rights of plaintiffs.[10]

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[7] March 31, 2016 Memorandum and Order, Dkt. No. 94 at 7.

[8] *Id*. at 6-7.

[9] *Id.* at 7-9.

[10] April 8, 2016 Memorandum and Order, Dkt. No. 102 at 5-6.

In denying Abbott's motions, the Court recognized Plaintiffs' evidence regarding a host of alleged inadequacies in the Depakote label outside of and unrelated to the spina bifida warning.[11] Moreover, as the Court acknowledged:

> Plaintiffs submit evidence that Abbott strategically diluted Depakote's warning and disseminated misleading information regarding the risks posed by Depakote. Plaintiffs also submit evidence that Abbott's failure to warn of the full extent of Depakote's teratogenic danger was profit-driven. Plaintiffs' evidence of Abbott's alleged dilution of Depakote's warning and its dissemination of misleading information associated with Depakote use during pregnancy creates a genuine issue of material fact regarding whether Abbott's actions rose to a level of culpable behavior.[12]

The reasoning and result set forth in this Court's Summary Judgment Orders are in agreement with every other Court in prior Depakote addressing this issue. Specifically, notwithstanding Abbott making the exact same arguments to confine the warnings issues to just spina bifida, both Judge Rosenstengel and Judge Herndon in the United States District Court for the Southern District of Illinois, and Judge Ohmer in the Missouri Circuit Court, 22nd Judicial District (City of St. Louis), specifically permitted evidence regarding the broader label deficiencies recognized by this Court in its Summary Judgment Orders and also acknowledged that Abbott's duty to warn is far broader than it argues. Abbott has a duty to provide adequate warnings to physicians regarding the use of its drug by pregnant women or women of childbearing age and of the danger that this drug presents to a fetus, and while the spina bifida warning is relevant, it is by no means dispositive or the only issue in the case.[13]

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[11] *Id.* at 6.

[12] *Id.*

[13] *See* April 14, 2014 Memorandum and Order, *J.B, et al., v. Abbott Laboratories, Inc.*, No. 13-cv-326-DRH-SCW, Dkt. No. 180 at 5-11 (S.D. Ill. April 14, 2014), attached hereto as **Exhibit A**. Also, as discussed below, these other Courts permitted Dr. Oakley to testify about a possible and reasonable pregnancy registry.

Notwithstanding the Court's Summary Judgment Orders, the Oakley Order appears to exclude Dr. Oakley's expert testimony regarding pregnancy registries based on the notion that the only relevant warning for Plaintiffs' claims is the 1 to 2 percent spina bifida warning in Abbott's Depakote label. In the Oakley Order, the Court stated: "In our case, Plaintiffs claim that Abbott failed to warn of the risk of birth defects with Depakote. The birth defect at issue is spina bifida. . . . Because Dr. Oakley cannot testify that a pregnancy registry would have altered the spina bifida warning on Depakote's label, the Court finds that Dr. Oakley's expert testimony that it was possible and reasonable for Abbott to have established such a registry would not assist the jury in determining any ultimate issue of fact."[14] As discussed above, while it is true that the spina bifida warning is certainly relevant, it is not the only relevant portion of Abbott's warning and, as the Court has already specifically held, does not completely "fulfill Abbott's duty under Missouri law to properly warn the doctor of the dangers involved."

As noted above, Plaintiffs file this brief because, notwithstanding the Court's recognition of Plaintiffs' broader claims in its Summary Judgment Orders, Plaintiffs anticipate Abbott will attempt to now use the Oakley Order as a basis for resuscitating its prior failed attempts to restrict Plaintiffs' failure to warn claims to just the spina bifida warning. Moreover, to the extent the Court clarifies this issue to reaffirm Plaintiffs' broader allegations, the relevance of Dr. Oakley's expert testimony regarding a pregnancy registry becomes apparent. Plaintiffs submit that Dr. Oakley will lay a proper foundation to show the jury that Abbott could have collected, and indeed specifically elected not to, additional information relating to the danger of this drug to a fetus, information that certainly would have led to the issuance of stronger warnings far earlier. (As the Court is aware, Abbott went decades without changing the substance of its birth defect

[14] May 6, 2016 Memorandum and Order, Dkt. No. 197 at 11, 13.

warning.) For this very reason, both Judge Rosenstengel and Judge Ohmer allowed Dr. Oakley to testify to the same in cases involving children diagnosed with spina bifida, even though Abbott raised the exact same arguments it does here.

With respect to his expert testimony regarding a pregnancy registry, Dr. Oakley's opinion is that establishing such a registry—which was possible and reasonable dating back to the 1980s[15]—would have allowed Abbott to obtain important and relevant information about the ***overall risk*** of birth defects associated with Depakote. While such a registry certainly would have included the collection of additional data regarding the risk of spina bifida, Dr. Oakley is not opining (nor would it even be a feasible or reasonable approach) that Abbott's possible and reasonable pregnancy registry solely collect data about just one birth defect—spina bifida—and simply disregard data regarding other birth defects associated with Depakote. And to the extent Abbott's pregnancy registry collected data regarding the ***overall risk*** of birth defects associated with Depakote, Dr. Oakley's expert testimony that it was possible and reasonable for Abbott to have established such a registry is undoubtedly relevant to the remaining fact issues recognized by the Court in its Summary Judgment Orders. Plaintiffs respectfully request that the Court allow Plaintiffs the opportunity to lay the proper foundation with Dr. Oakley.

Abbott has similarly attempted to exclude Dr. Oakley's pregnancy registry opinion in prior Depakote cases on the same "spina bifida warning" basis alleged in this case. As noted

[15] Abbott's corporate representative similarly provided no explanation regarding why Abbott could not have done a registry during this time period. *See, e.g.*, Deposition of Dr. James Embrescia, April 16, 2014, at 116:22-117:2, 117:6-117:9 ("Q. And -- and I appreciate what you offer me, but that's not what I've asked, whether it was commonly done. I asked the question: Is there any reason you can offer to the court and jury why Abbott could not have done a registry prior to 1996? A. I -- I think that was the – I'm sorry. I think that was the answer is that I don't think that it was something that people thought about doing back in those days across company."); *id.* at 120:17-19; 120:22-24 ("Q. You cannot offer any reason why Abbott would have been prevented from doing a registry prior to 1996, is that correct? A. I'm not aware of any epidemiology reason, which I think is what you asked me, that you couldn't do a registry.")

above, both Judge Rosenstengel in the United States District Court for the Southern District of Illinois and Judge Ohmer in the Missouri Circuit Court, 22nd Judicial District (City of St. Louis), permitted evidence regarding the broader label deficiencies recognized by this Court in its Summary Judgment. Based on the recognition of these broader claims and on Abbott's continuous duty to collect, analyze and communicate data regarding its drug, both courts denied Abbott's attempts to exclude Dr. Oakley's pregnancy registry opinion. Specifically, Judge Rosenstengel held:

> Abbott also argues that Dr. Oakley speculates that a pregnancy registry would have yielded meaningful results. The purpose of the registry would have been to learn about the risks associated with the use of Depakote during pregnancy. Dr. Oakley opines that a pregnancy registry initiated by Abbott would have revealed more information about Depakote's teratogenicity at an earlier point in time (Doc. 105, p. 17). He opines that the registry would have "elaborated on the risks to a fetus posed by valproic acid and also a comparison of that risk to other antiepileptic drugs that were being used in similar populations. . . . Overall, the Court finds that it is not speculative that a pregnancy registry would have revealed more information relating to Depakote's risks at an earlier point in time. It is very likely that more information relating to Depakote's risks would have yielded meaningful results by allowing Abbott to better understand the harm caused by the drug.[16]

In finding that Dr. Oakley's opinions regarding the pregnancy registry were indeed relevant, Judge Rosenstengel held:

> Thus, the ways in which Abbott could have monitored the safety (or adverse effects) of Depakote (i.e. via a pregnancy registry) is relevant to the question of whether Abbott satisfied its continuous duty to keep abreast of scientific developments touching on Depakote, to notify the medical profession of any additional safety information discovered from Depakote's use, and to warn of risks or dangers that it "knew or should have known." *Proctor*, 682 N.E.2d at 1211; *Woodill*, 402 N.E.2d at 198-200. It is, of course, also relevant to whether Abbott satisfied its duty of reasonable care.
>
> Further, the ways in which Abbott could have monitored the safety of Depakote in pregnant women are not exactly something that would be known to a layperson.

[16] February 13, 2015 Memorandum and Order, *D.W.K., et al., v. Abbott Laboratories, Inc.*, No. 14-CV-847-NJR-SCW, Dkt. No. 281 at 24-25 (S.D. Ill. February 13, 2015), attached hereto as **Exhibit B** (relevant portions highlighted).

> Thus, Dr. Oakley may testify regarding the fact that Abbott could have utilized a pregnancy registry in order to monitor the safety of Depakote, which may by chain of inference assist the jury in drawing conclusions regarding whether Abbott satisfied its duty to provide an adequate warning about the risks of Depakote.[17]

As noted, Plaintiffs are filing this brief because it has become clear that Abbott is going to attempt to use the Oakley Order to restrict the presentation of Plaintiffs' case in a manner that is inconsistent with Missouri law and Abbott's duty to warn, and also specifically conflicts with the Court's prior orders denying Abbott's summary judgment motions. This has potentially far-reaching implications for this case. Plaintiffs appreciate the Court's consideration of these issues.

Dated: May 17, 2016

Respectfully submitted,

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[17] *Id.* at 28-29.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 17th day of May, 2016, I electronically filed the foregoing document, along with its related exhibits, with the Clerk of the Court using the CM/ECF system, which sent notification of the filing to all counsel of record.

/s/Daniel A. Raniere